Island Pharmacy Services, Inc.

Prescription Compounding Specialists

P.O. Box 1412
Woodruff, WI 54568
715-358-7712 Fax 715-358-7021

Toll Free 800-328-7060

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Dockets Management Branch (HFA-305)
FDA
5630 Fishers Lane
Room 1061
Rockville, MD 20852

I am writing to give my input on your proposed modification of the section of the FDA Modernization Act of 1997 that concerns the interstate distribution of compounded medications. The proposal, as I understand it, would limit interstate sales of compounded medications to a maximum of 20% of total sales.

I would submit that this proposal is discriminatory and arbitrary. Nowhere have I seen any justification for the magic number of 20% of sales. Why not 40%, or 80%? And a percentage of sales of what? Prescription sales, or total store sales? Who is going to be authorized to audit my private store records to make this determination? When did the FDA become endowed with the authority that would limit how much we can sell? How is a limit on total sales connected with protecting the safety of medicine?

I have been reading recently about the proliferation of mail-order pharmacies, including internet pharmacies. One article covered the expansion of the PCS Health Systems mail-order pharmacy in Birmingham, AL which will employ between 400 and 500 people and expects to fill 150,000 prescriptions per week! How many of these prescriptions will be outside a 50 mile radius? How can the FDA grant approval for mail-order and internet pharmacies to compete with local retail pharmacies while at the same time seek to restrict the sale of valid compounded prescriptions interstate? This is a classic case of the agency overstepping its authority and acting in restraint of trade in a manner that opens itself for a class action discrimination lawsuit.

The prescription medications our pharmacy compounds are, by definition, unique medications unavailble elsewhere unless they are specially prepared. We compound a large number of prescriptions for patients outside a 50-mile radius for several important reasons. First, there are many cases where there is literally no other pharmacy in the area willing to compound the drug. From a practical standpoint, if there is not another compounding pharmacy in the patient's town and they are forced to drive to another town, even if it is only 10 or 20 miles away, it is usually faster and more convenient to have the medication mailed to them. And if the prescription is being mailed to them anyway what is the difference between having it mailed from 20 miles away or 200 miles away? Again, the limitation of 50 miles is totally arbitrary.

Secondly, even if there was a local pharmacy that could compound the drug, if it took the patient several days longer to receive the medication and/or cost them more to purchase the prescription then how would this restriction be of benefit to the consumer? Prescription compounding is a specialty, and like all other specialties there exists certain economies of scale. Pharmacies that "dabble" in compounding are unlikely to stock as wide an inventory of drugs as specialists, nor are they likely to have the time or expertise of specialists to properly prepare the medication in a totally professional manner. Consequently, a restriction on interstate delivery of compounded medications will only serve to lengthen the delivery time and

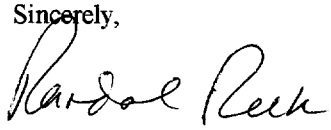
increase the final cost to the consumer, which sets the FDA up for another class action lawsuit on behalf of the affected population of patients.

A prescription from any doctor in the U.S. is valid in our pharmacy. What would you propose that we tell doctors who call in prescriptions for compounded medications? "We cannot fill your prescription this month because we have exceeded our 20% FDA-imposed quota. Please have your patients get by until next month and we will see if we can accomodate them then." The Act of 1997 was purported to establish prescription compounding as a legitimate function of pharmacy, outside the authority of the FDA. By restricting the sale of compounded drugs the FDA would not only be infringing on the rights of pharmacies to engage in a clearly defined lawful enterprise, it would also be restricting the rights of doctors to practice medicine in a manner that puts the needs of the patients first. In our practice alone there are close to ten thousand doctors for whom we have filled prescriptions that would argue strongly that such restrictions have no possible benefit for the patient. Restraint of their abilities to practice medicine is also grossly discriminatory.

We live in a era of specialization. Patients are often referred to specialists more than 50 mile form home in order to receive the best possible treatment. This regulation would restrict the patient's ability to have a specialized compounded prescription prepared by a pharmacy more than 50 miles from home, even if there were no other compounding pharmacies in the area, and even if the patient would have to pay more or wait longer to get the required drug from a pharmacy that was closer. Again, who is being harmed? The FDA would be imposing a "back door" restraint on the legitimate practice of pharmacy and no one would benefit.

In conclusion, I submit that this proposed restriction will harm the patient, harm the practice of medicine, and harm the profession of pharmacy. In that context I contend that it should be dropped before it ever receives any further consideration.

Sincerely,



Randal Reek
president